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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/826,420	04/16/2004	Kyungyoon Min	F-6097 (9360-0145.01)	9851

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EXAMINER	
DEAK, LESLIE R	

ART UNIT	PAPER NUMBER
3761	

MAIL DATE	DELIVERY MODE
08/12/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/826,420	MIN ET AL.	
	Examiner	Art Unit	
	LESLIE R. DEAK	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 June 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-7,10-14, 20, 21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-7,10-14,20 and 21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *12 February 2007* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 19 June 2008 has been entered.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1, 3-6, 10-12, 14, 20, and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,632,191 to Headley et al in view of US 4,985,153 to Kuroda et al.

In the specification and figures, Headley discloses the method substantially as claimed by Applicant. With regard to claims 1, 3, 20, and 21, Headley discloses a method for collecting and separating whole blood comprising the steps of providing a disposable blood separation set (see FIG 1) that mounts on a reusable separator and

control unit 20 (see column 3, lines 15-25). The disposable set comprises a cannula 10 or fluid flow path for communicating with a source, and a processing chamber 21.

Headley discloses the steps known in the prior art of connecting cannula or port 10 to a donor, flowing fluid from the donor to an initial container 12 with anticoagulant, disconnecting the patient from the set before blood is processed, mounting the set in a centrifuge, processing the blood through in processing chamber 13, processing the collected blood to separate into the desired components, and disconnecting the donor from the system before the separation process is complete (see column 1, lines 25-60).

Headley discloses the steps of flowing fluid from a donor via cannula 10 directly into a processing chamber/rotor 21, processing the collected blood in the rotor to separate it into desired components, and disconnecting the donor from the system after processing begins, but before the plasma is urged from the rotor, so before the processing ends (see column 4, lines 1-10).

Headley fails to disclose that the fluid source or donor is disconnected from the fluid circuit after a portion of the separated components is removed from the processing chamber but before all the blood in the circuit is processed in the processing chamber. However, it has been held that the selection of any order of performing process steps is obvious in the absence of new or unexpected results. See MPEP § 2144.04 (IV)(C). In the instant case, Applicant has not provided any evidence that the order in which the blood is processed and the patient is removed from the fluid circuit provides any new or unexpected results. Accordingly, it is the position of the Examiner that the order of the

steps claimed by Applicant is an obvious variation of the order of the steps disclosed by Headley.

With regard to Applicant's claimed step of mounting the disposable circuit onto the controller, Headley discloses that the disposable set is mounted in the reusable assembly prior to connecting the set to a patient. However, the language of the claim does not set forth a specific order of the steps performed in the method. It is improper to read a specific order of steps into method claims where the language of the method claims did not impose a specific order on the steps and the specification did not require a particular order (see MPEP 2111.01(II)). Applicant's specification, at paragraphs 0021, indicates that the disposable set may be mounted on the reusable device before or after the set is connected to the donor. As such, since Headley discloses all the steps in the claimed method and Applicant does not specify an order of the claimed steps, it would have been obvious to rearrange the steps disclosed by Headley to arrive at the claimed method.

Headley fails to disclose the step of flowing the collected donor blood into an initial collection chamber before passing it to the processing chamber. However, such initial collection containers are well-known in the art, as disclosed by Headley and Kuroda. Kuroda discloses a method and apparatus for collecting and processing blood comprising a blood collector means 1 that may comprise a cannula 16, connector 18, and blood collection bag 17 with anticoagulant 18. Blood is collected from the patient via cannula 16, mixed with anticoagulant in collection bag 17, and passed to the remainder

of the processing apparatus, including processing chamber 3, via connector 8 (see FIG 6, column 13, lines 8-48).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to add the step of passing the collected blood through an initial container on its way to the processing chamber, as disclosed by Kuroda, to the blood collection and processing method disclosed by Headley in order to provide a chamber for thorough mixing of blood with anticoagulant, as suggested by Kuroda.

With regard to claims 4-6, 14, Headley discloses that the rotor or collection chamber in the disclosed embodiment has a variable volume (see column 3, lines 15-34). It has been held that where the general conditions of a claim are disclosed in the prior art, it is within the skill of a worker in the art to discover the optimum or workable ranges by routine experimentation. See MPEP 2144.05(II)(A). Since Headley specifically discloses that the volume of blood collected may vary from patient to patient, it is the position of the examiner that the amount of whole blood collected is a result-effective variable, the optimization of which is within the skill of a worker in the art.

With regard to claim 10, Headley discloses that the blood source is a “donor,” (see column 1, lines 25-30), which is well-known in the art to comprise a human donor (see US 5,906,589 to Gordon et al that discloses apheresis blood supply as typically a human donor/patient at column 3, lines 55-60).

With regard to claims 11 and 12, Headley discloses that the system and method may be use to separate all the collected blood into constituent components

simultaneously (see column 4, lines 20-30) or sequentially, wherein plasma is removed from the blood before RBC separation (see column 4, lines 13-16).

4. Claims 7 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,632,191 to Headley et al in view of US 4,985,153 to Kuroda et al, further in view of US 6,743,192 to Sakota et al.

In the specification and figures, Headley and Kuroda disclose the method substantially as claimed by Applicant (see rejection above) with the exception of providing additional whole blood bags and pooling whole blood before processing. Sakota discloses a blood apheresis apparatus and method comprising a disposable fluid circuit with a phlebotomy needle 24 that connects to a donor. The phlebotomy needle may be replaced with a whole blood bag in case whole blood is to be pooled and then supplied to the apheresis system (see column 6, lines 55-65) in order to increase the amount of whole blood processed in a single round of apheresis (see column 2, line 56 to column 3, line 37). Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to add the additional containers and pooling whole blood as disclosed by Sakota in the process disclosed by Headley in order to increase the volume of whole blood processed, as taught by Sakota.

Response to Arguments

5. Applicant's amendment and arguments filed 10 June 2008 have been entered and considered.

6. Applicant's arguments have been fully considered but they are not persuasive.

7. Applicant argues that the Headley reference does not disclose the specific order in which the blood is collected, processed, urged from the rotor, source is disconnected, and processing continues, as claimed by Applicant.

8. The Examiner agrees that Headley does not disclose the claimed order of the steps., However, it has been held that the selection of any order of performing process steps is obvious in the absence of new or unexpected results. See MPEP § 2144.04 (IV)(C). In the instant case, Applicant has not provided any evidence that the order in which the blood is processed and the patient is removed from the fluid circuit provides any new or unexpected results. In fact, the instant specification indicates that the order of the steps allows for reduced downtime for the donor, since the donor is disconnected before processing finishes. However, in an embodiment disclosed by Headley, the donor may be disconnected from the fluid circuit before any processing begins, ensuring an even shorter patient downtime. Accordingly, it is the position of the Examiner that the order of the steps disclosed by the prior art provides a result that is the same as that disclosed by Applicant, suggesting that Applicant's claimed order provides no new or unexpected results. Accordingly, the claims are unpatentable over the prior art.

Conclusion

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LESLIE R. DEAK whose telephone number is (571)272-4943. The examiner can normally be reached on Monday - Friday, 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leslie R. Deak/
Primary Examiner
Art Unit 3761
11 August 2008